

Office Action Summary

Application No.

10/507,380

Applicant(s)

ACHIRON ET AL.

Examiner

Jennifer Dunston

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-8,10-17 and 22-35 is/are pending in the application.
- 4a) Of the above claim(s) 5-8,10-12,16,17 and 22-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4 and 13-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. <u>20090618</u> . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/28/2009</u> . | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/5/2009 has been entered.

Receipt is acknowledged of an amendment, filed 6/5/2009, in which claims 1 and 13-15 were amended. Claims 1, 4-8, 10-17 and 22-35 are pending.

Election/Restrictions

Applicant's election without traverse of Group I in the reply filed on 11/27/2007 is acknowledged. Applicant's election without traverse of species (A) detection of nucleic acid (claim 13), and (B) all of the genes in Table II (claim 9) in the reply filed on 11/27/2007 is acknowledged.

Claims 5-8, 10-12, 16, 17 and 22-35 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/27/2007.

Claims 1, 4 and 13-15 are under consideration.

Information Disclosure Statement

Receipt of an information disclosure statement, filed on 6/28/2009, is acknowledged.

The signed and initialed PTO 1449 has been mailed with this action.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60/365,800, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The specification of Application No. 60/365,800 does not describe the genes that show a substantial or significant difference in expression between a subject with multiple sclerosis and a normal, healthy individual. The specification of the 60/365,800 application describes genes that are differentially expressed between subjects with relapse of multiple sclerosis and remission of multiple sclerosis. The specification of the

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60/365,800 application does not describe the genes of instant Table II, for example. Thus, the specification does not provide adequate support or enablement for the claimed method of diagnosing a subject with multiple sclerosis, the method comprising determining a level of expression of at each of the genes listed in Table II, wherein said level of expression is compared to a normal level of expression.

Claims 1, 4 and 13-15 have an effective filing date of 3/13/2003, which is the filing date of PCT/IL03/00208.

Specification – Objections & Response to Arguments

The substitute specification filed 6/5/2009 has been entered.

The substitute specification filed 6/5/2009 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Affymetrix probe ID numbers (e.g., column 2 in Table II) and the newly added sequences.

The reply filed 6/5/2009 indicates that the specification has now been amended to provide the Affymetrix identification codename for the partial target sequence for which the Affymetrix probes were designed to hybridize with for all the Tables therein. The response notes that it is possible to use Affymetrix software available at the time of filing to ascertain the target sequences for each gene. Applicant asserts that the provision of the code names enables anyone of ordinary skill in the art to carry out the presently claimed invention.

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The reply also notes that the amended specification teaches that the U95Av2 array was used for Tables I-IV (page 38, line 16). Further, the response notes that the U133A array was used for Table V (page 38, line 17 of the amended specification). The response notes that the code names of the potential target sequences were not disclosed in the original specification. However, the response asserts that the sequences were available to the public at the time of filing. Further, the response asserts that the sequences added to the specification were the most up-to date sequences known at the time of filing of the application and were the sequences used by Affymetrix to design their probes. Thus, the response asserts that the addition of code names and sequences do not introduce new matter.

As admitted by Applicant the originally filed specification does not contain the code names and target sequences that were introduced into the specification by the amendment filed 6/5/2009. Material may be added to the specification to correct an improper incorporation by reference, where the application as filed clearly conveys intent to incorporate the material by reference, and the material was sufficiently described to uniquely identify the document. In the instant case, no clear intent to incorporate the Affymetrix code names and sequences could be found in the originally filed specification. Even if mention of specific Affymetrix arrays was made, mere reference to material does not convey intent to incorporate the material by reference. Furthermore, Applicant indicates that the sequences incorporated into the specification were the most up-to date sequences known at the time of filing of the application. The specification does not uniquely identify the most recent sequences as sequences to be incorporated, and the presence of multiple versions of a sequence prior to filing of the application precludes a unique

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identification of the sequence. Further description would be required in the originally filed specification to specifically incorporate the most up-to date sequence.

Applicant is required to cancel the new matter in the reply to this Office Action.

The attempt to incorporate subject matter into this application by reference GenBank Accession numbers is ineffective because the specification attempts to incorporate gene sequences identified as entries in an electronic database (page 115, lines 3-8). The attempt to incorporate subject matter into the patent application by reference to a hyperlink and/or other forms of browser-executable code is considered to be an improper incorporation by reference. See 37 CFR 1.57(d) and MPEP § 608.01(p), paragraph I regarding incorporation by reference.

The incorporation by reference will not be effective until correction is made to comply with 37 CFR 1.57(b), (c), or (d). If the incorporated material is relied upon to meet any outstanding objection, rejection, or other requirement imposed by the Office, the correction must be made within any time period set by the Office for responding to the objection, rejection, or other requirement for the incorporation to be effective. Compliance will not be held in abeyance with respect to responding to the objection, rejection, or other requirement for the incorporation to be effective. In no case may the correction be made later than the close of prosecution as defined in 37 CFR 1.114(b), or abandonment of the application, whichever occurs earlier.

Any correction inserting material by amendment that was previously incorporated by reference must be accompanied by a statement that the material being inserted is the material incorporated by reference and the amendment contains no new matter. 37 CFR 1.57(f).

Applicant's arguments filed 6/5/2009 have been fully considered but they are not persuasive.

The reply filed 6/5/2009 indicates that the specification was amended to include the addition of code names for the partial target sequences and to provide SEQ ID NOs for the genes listed in Table II. The amendment does not correct the improper incorporation by reference.

Material may be added to the specification to correct an improper incorporation by reference, where the application as filed clearly conveys intent to incorporate the material by reference, and the material was sufficiently described to uniquely identify the document. In the instant case, no clear intent to incorporate the Affymetrix code names and sequences could be found in the originally filed specification. Even if mention of specific Affymetrix arrays was made, mere reference to material does not convey intent to incorporate the material by reference. Furthermore, Applicant indicates that the sequences incorporated into the specification were the most up-to date sequences known at the time of filing of the application. The specification does not uniquely identify the most recent sequences as sequences to be incorporated, and the presence of multiple versions of a sequence prior to filing of the application precludes a unique identification of the sequence. Further description would be required in the originally filed specification to specifically incorporate the most up-to date sequence.

Accordingly, the presently amended specification does not correct the improper incorporation of GenBank accession numbers.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4 and 13-15 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.** This rejection was made in the Office action mailed 12/15/2008 and has been rewritten to address the amendment filed 6/5/2009.

The claims require determining a level of expression of the genes listed in Table II. In the reply filed 6/5/2009, Table II was amended by providing a substitute specification. The added material which is not supported by the original disclosure is as follows: Affymetrix probe ID numbers (e.g., column 2 in Table II) and the newly added sequences.

The reply filed 6/5/2009 indicates that the specification has now been amended to provide the Affymetrix identification codename for the partial target sequence for which the Affymetrix probes were designed to hybridize with for all the Tables therein. The response notes that it is possible to use Affymetrix software available at the time of filing to ascertain the target sequences for each gene. Applicant asserts that the provision of the code names enables anyone of ordinary skill in the art to carry out the presently claimed invention.

The reply also notes that the amended specification teaches that the U95Av2 array was used for Tables I-IV (page 38, line 16). Further, the response notes that the U133A array was used for Table V (page 38, line 17 of the amended specification). The response notes that the

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code names of the potential target sequences were not disclosed in the original specification.

However, the response asserts that the sequences were available to the public at the time of filing. Further, the response asserts that the sequences added to the specification were the most up-to date sequences known at the time of filing of the application and were the sequences used by Affymetrix to design their probes. Thus, the response asserts that the addition of code names and sequences do not introduce new matter.

As admitted by Applicant the originally filed specification does not contain the code names and target sequences that were introduced into the specification by the amendment filed 6/5/2009. Material may be added to the specification to correct an improper incorporation by reference, where the application as filed clearly conveys intent to incorporate the material by reference, and the material was sufficiently described to uniquely identify the document. In the instant case, no clear intent to incorporate the Affymetrix code names and sequences could be found in the originally filed specification. Even if mention of specific Affymetrix arrays was made, mere reference to material does not convey intent to incorporate the material by reference. Furthermore, Applicant indicates that the sequences incorporated into the specification were the most up-to date sequences known at the time of filing of the application. The specification does not uniquely identify the most recent sequences as sequences to be incorporated, and the presence of multiple versions of a sequence prior to filing of the application precludes a unique identification of the sequence. Further description would be required in the originally filed specification to specifically incorporate the most up-to date sequence.

The original specification, drawings and claims were thoroughly reviewed and no support could be found for the amendment to include the sequence listing and sequence identifiers in

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each of the tables. Accordingly, the amendment is a departure from the specification and claims as originally filed, and the GenBank entries do not provide support for the amendment.

Response to Arguments - 35 USC § 112

With respect to the rejection of claims 1, 4 and 13-15 under 35 U.S.C. 112, first paragraph (new matter), Applicant's arguments filed 6/5/2009 have been fully considered but they are not persuasive.

The reply filed 6/5/2009 indicates that the specification has now been amended to provide the Affymetrix identification codename for the partial target sequence for which the Affymetrix probes were designed to hybridize with for all the Tables therein. The response notes that it is possible to use Affymetrix software available at the time of filing to ascertain the target sequences for each gene. Applicant asserts that the provision of the code names enables anyone of ordinary skill in the art to carry out the presently claimed invention.

The reply also notes that the amended specification teaches that the U95Av2 array was used for Tables I-IV (page 38, line 16). Further, the response notes that the U133A array was used for Table V (page 38, line 17 of the amended specification). The response notes that the code names of the potential target sequences were not disclosed in the original specification. However, the response asserts that the sequences were available to the public at the time of filing. Further, the response asserts that the sequences added to the specification were the most up-to date sequences known at the time of filing of the application and were the sequences used

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by Affymetrix to design their probes. Thus, the response asserts that the addition of code names and sequences do not introduce new matter.

These arguments are not found persuasive, because the originally filed specification does not contain the code names and sequences now added to the specification, nor does the originally filed specification contain an incorporation by reference of the newly added material. Thus, the material added to the specification does not properly correct an improper incorporation by reference.

For these reasons, and the reasons made of record in the previous office actions, the rejection is maintained.

Applicant's arguments, see pages 17-21, filed 6/5/2009, with respect to the rejection of claims 1, 4 and 13-15 under 35 U.S.C. 112, first paragraph (enablement), have been fully considered and are persuasive. The previous rejection of claims 1, 4 and 13-15 has been withdrawn.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Dunston whose telephone number is 571-272-2916. The examiner can normally be reached on M-F, 9 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jennifer Dunston/
Examiner
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